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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,934

06/30/2006

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F-9156

2143

28107 7590 07/14/2009
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EXAMINER

BOESEN, AGNIESZKA

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

07/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,934	Applicant(s) SCHUBERT, ULRICH	
	Examiner AGNIESZKA BOESEN	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 and 50-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-48 and 50-73 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election of group III claims 33, 34, 37-48 and 50-71 on March 26, 2009 is acknowledged. Upon further consideration the restriction requirement of January 23, 2009 is withdrawn and a new restriction requirement is set forth below. Any inconvenience is regretted.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-21, 72 and 73, drawn to a pharmaceutical composition comprising an agent for inhibition of assembly and maturation of virus structure proteins comprising as an active ingredient at least one inhibitor of cellular chaperones or a chemical chaperone.

Group II, claim(s) 22-32, 35 and 36 drawn to a method for inhibition of the assembly and maturation of virus structure proteins in an organism and a method for reduction of number of infected virus-producing cells comprising administering a pharmaceutical preparation of claim 1.

Group III, claim(s) 33, 51 and 52, drawn to a method for treating or preventing HCV-induced and non-viral factor induced liver cell carcinomas.

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Group III, claim(s) 33, drawn to a method for treating or preventing medicine induced liver carcinomas.

Group IV, claim(s) 33, drawn to a method for treating or preventing genetically conditioned liver carcinomas.

Group V, claim(s) 33, drawn to a method for treating through the environment induced liver carcinomas.

Group VI, claim(s) 34, drawn to a method for elimination of liver carcinoma cells.

Group VII, claim(s) 37, drawn to a method for reduction of number of infected cell.

Group VIII, claim(s) 38, 39 and 48 drawn to a method for treatment of a human who may be exposed to Flavivirus.

Group X, claim(s) 40-42, drawn to a method for treatment of a human who may be exposed to Flavivirus.

Group XI, claim(s) 43 and 44, drawn to a method for treatment of humans having co-infections of HCV and HIV-1 and HIV-2.

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Group XII, claim(s) 45-47 drawn to a method for prevention of a re-infection with HCV during cell therapies of a liver or organ transplantation comprising administering a pharmaceutical preparation of claim 1.

Group XIII, claim(s) 50, drawn to a method for inhibition of an already established infection.

Group XIV, claim(s) 53 and 54, drawn to a method for treatment of a co-infection with HBV and HIV-1.

Group XV, claim(s) 55-57 and 60 drawn to a method for inhibition of the release maturation and replication of hepatitis viruses.

Group XVI, claim(s) 57-60 drawn to a method for inhibition of the release maturation and replication of retroviruses.

Group XVII, claim(s) 61 drawn to a method of hindering in retroviruses in an organism proteolytic processing of the structural Gag proteins.

Group XVIII, claim(s) 62 drawn to a method of inhibiting in an organism release, maturation and replication of Spuma viruses.

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Group XIX, claim(s) 62 drawn to a method of inhibiting in an organism release, maturation and replication of Spuma viruses.

Group XX, claim(s) 62 drawn to a method of inhibiting in an organism release, maturation and replication of Mammalian C-Type Onco-viruses.

Group XXI, claim(s) 62 drawn to a method of inhibiting in an organism release, maturation and replication of BLT (Bovine Leukemia Viruses) or Leukemia viruses.

Group XXII, claim(s) 62 and 63 drawn to a method of inhibiting in an organism release, maturation and replication of HTLV or Leukemia viruses.

Group XXIII, claim(s) 62 drawn to a method of inhibiting in an organism release, maturation and replication of RSV viruses.

Group XXIV, claim(s) 62 and 64 drawn to a method of inhibiting in an organism release, maturation and replication of Lenti viruses.

Group XXV, claim(s) 66-71 drawn to a method of treatment of AIDS.

The inventions listed in groups I-XXV do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features for the following reasons: the shared technical feature of the claimed invention is a pharmaceutical composition comprising an agent for inhibition of assembly and maturation of virus structure proteins comprising cellular chaperones or chemical chaperones, a method for inhibition of the assembly and maturation of virus structure proteins, and a method for prophylactic treatment of a human comprising administering a pharmaceutical preparation.

Hung et al. (Journal of Virology, 2002, Vol. 76, p. 1379-1390) disclose that a GA specific inhibitor of Hsp90 inhibits the replication of vaccinia virus (see the entire document).

Since Applicant's invention does not contribute a special technical feature when viewed over the prior art they do not have a single inventive concept and thus the claims lack unity of invention. Therefore, the instant invention lacks Unity of Invention and restriction is set forth as it applies to U.S. practice.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the**

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patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on Monday- Friday from 9:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/
Examiner, Art Unit 1648